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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,641	09/29/2004	Christian Drohmann	53383	4300

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EXAMINER	
POPOVICS, ROBERT J	
ART UNIT	PAPER NUMBER
1797	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/509,641	DROHMANN ET AL.	
	Examiner	Art Unit	
	/Robert James Popovics/	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed through **May 19, 2009 - RCE**

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date **May 19, 2009**
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on **May 19, 2009** has been entered.

Election/Restrictions

Applicants' election without traverse is noted:

> In compliance with the requirements of 37 C.F.R. §1.143, applicants provisionally elect group 1, "Polyolefins" of the "A" species and group 5 "Crosslinked Polyvinyllactams" of the "B" species. Claims 11 – 27 are readable on the elected species. This provisional election is submitted without traverse.

Claim Rejections - 35 USC § 103

Claims **11-27** are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of **Butterworth (US 3,958,023)** and/or **Van Den Eynde (US 6,117,459)** and/or **BASF's "60th Anniversary of Povidone."**

Butterworth discloses the use of **PVPP** admixed with conventional filter aids to treat liquids. (see column 2 and claims 1 and 4 of **Butterworth**).

BASF ExAct

page 4 – No.2, July 1999

More densely crosslinked PVP is prepared by copolymerization of N-vinylpyrrolidone with bifunctional monomers. Because of the combination of high water uptake and insolubility, swelling is observed with crosslinked PVP when exposed to water while soluble PVP simply dissolves.

The popcorn polymerization – bulk polymerization of N-vinylpyrrolidone either in presence of alkali metal hydroxide above 100°C or in presence of small amounts of bifunctional monomers at 100°C – leads to highly crosslinked PVP particles with a specific surface area of a few square meters per gram. This popcorn PVP, Crospovidone, finds important use as tablet disintegrant, as an agent for clarifying beverages and as active ingredient for stomach and gastrointestinal diseases. In contrast to soluble PVP, complexes of crosslinked PVP with high complexation constants enable the extraction of the complexed molecule. The usefulness of crosslinked PVP for gastrointestinal diseases is based on the following properties:

[illegible]

Complex formation of crosslinked PVP with tannin is of interest both in pharmacology and in beverage technology (K. J. Siebert, P. Y. Lynn, J. Am. Soc. Brew. Chem. 55, 73 (1997); O. Horn, W. Otter, J. Pharm. Sci. 71, 820 (1982)). Tannin is a biopolymer with polyphenol structures. The complexation constant of tannin with Kollidon CL is >1000 L mol^{-1} (in 0.1 N hydrochloric acid).

Particle size distribution plays a more crucial role for the application properties of crosslinked PVP as compared to soluble grades. The properties of Kollidon grades as a disintegrant for tablets vary with particle size (**Table 3**) (V. Bühler, Polyvinylpyrrolidone for the pharmaceutical industry, BASF, Ludwigshafen 1998). In tablets obtained from Kollidon by compression the disintegration time decreases with the particle size of the PVP used for the formulation. Like soluble PVP, Kollidon CL-M is capable of stabilizing suspensions, such as antibiotics, antacids, vitamin preparations and topical formulations.

Lately it has been demonstrated, that pH-controlled drug release is possible from PVP/Polyacrylic acid interpenetrating networks (J. R. Young, T. K. Reed, J. Appl. Polym. Sci. 68, 431 (1998)). Radiation-cured hydrogels of PVP, polyethylene glycol, and agar have many desirable properties for using as wound dressings (K. G. Lugao et al., Radiat. Phys. Chem. 52, 319 (1998)).

3 Polymer/Drug Melt Extrusion

As a result of close collaboration over the past ten years, Knoll AG and its parent company BASF have developed a patent-protected novel pharmaceutical manufacturing technology: drug is incorporated by melt extrusion in a matrix consisting of a pharmaceutical polymer. Due to its thermoplasticity and

Properties of insoluble PVP grades (**Table 3**)

Property	Crospovidone	Kollidon CL	Kollidon CL-M	Crospovidone [illegible]
Particle size [illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Bulk density	[illegible]	[illegible]	[illegible]	[illegible]
Specific surface area [illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Hydration capacity [illegible]	[illegible]	[illegible]	[illegible]	[illegible]

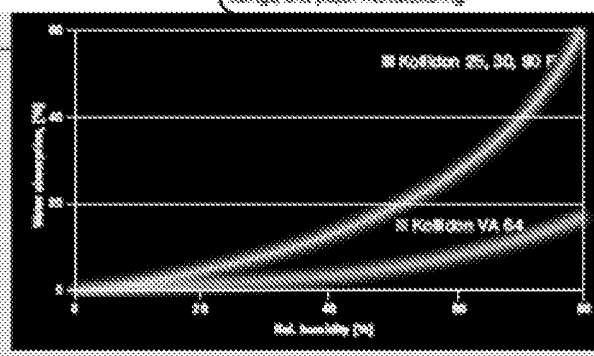
balanced aqueous solubility properties, Kollidon grades have been found to provide a comprehensive and universal base for various types of drugs. After melt extrusion, the active drug can be present in the extrudate in one or two forms: as a crystal suspended in the hardened Kollidon matrix, or as a molecule dissolved in the polymer during the melting phase and remaining dissolved in the finished product – a "solid solution". Melt extrusion technology paves the way for benefits in therapy (**Figure 5**).

[illegible]

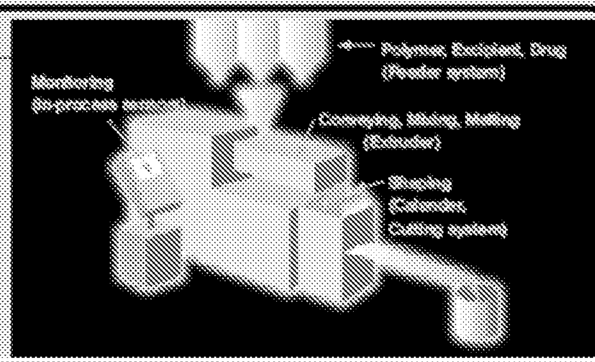
4 Miscellaneous Applications

Further pharmaceutical, biomedical and biochemical applications cover protein isolation and protein stabilization (J. F. Carpenter et al., ACS Symp. Ser. 567, 134 (1994)), gene therapy (K. Anwer et al., Human Gene Therapy 9, 659 (1998)), cancer therapy (F. Kerch et al., Oncology Reports 5, 103 (1998)), and reproduction biology (J. L. Davidson, J. Robinson, Human Reproduction 11, 2197 (1996)). Besides pharmaceutical uses, technical grades of PVP are used throughout the industry. Applications cover cosmetics and toiletries, beverage filtration, photographic products, dyeing applications and inks, detergents, dispersions, suspensions and emulsions, adhesives, paints and coatings, and paper manufacturing.

Hygroscopicity of Kollidon VA 64 and Kollidon 25, 30 or 90 F for comparison, after 7 days at 25 °C (**Figure 4**)



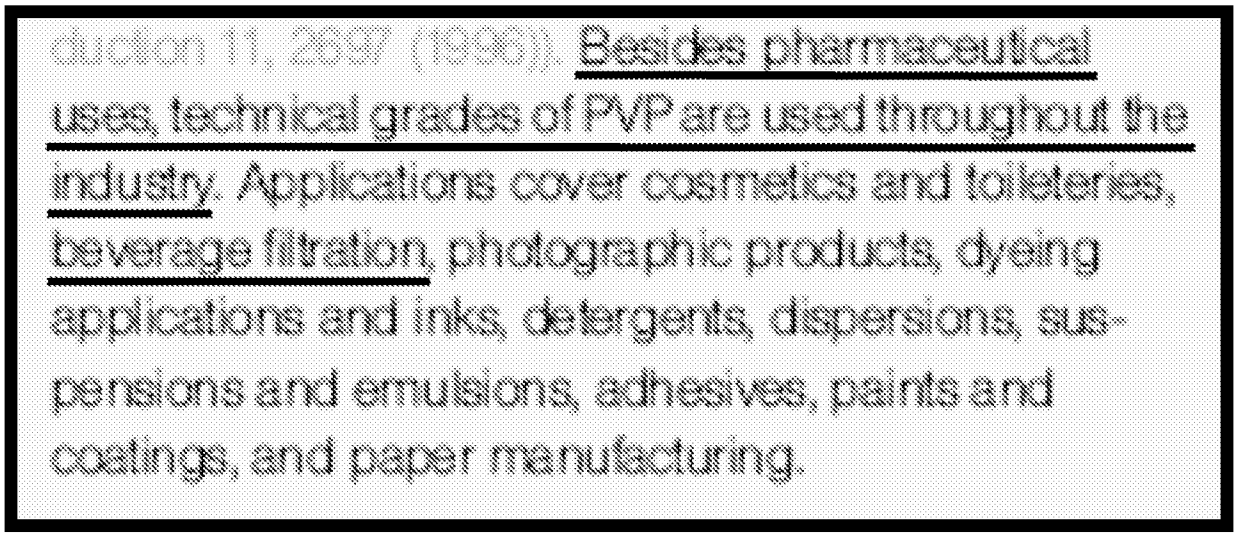
Polymer/Drug Melt Extrusion. Product is either tablet, granules, pellet, sheet ... (**Figure 5**)



Van Den Eynde (US 6,117,459) discloses the use of **polyolefins**, for example, **polypropylene** and **polyethylene** (see **claim 8** of **Van Den Eynde**) and **PVPP** (see **claim 12** of **Van Den Eynde**) in the treatment of **beer**. **Van Den Eynde,** like **Butterworth**, teaches that it is preferred that the filtration and stabilization steps be carried out simultaneously. See **column 4, lines 45-55** of **Van Den Eynde**:

> In one preferred embodiment of the invention, the process further includes a stabilization step. This step can be carried out during or after the filtration step proper, using filtration adjuvants conventionally employed, including silica gels, gallic tannins, etc. If the stabilization is carried out after the filtration, proteolytic enzymes and polyvinylpyrrolidone (PVPP) are generally used, preferably in a form that can be regenerated.
>
> The stabilization is advantageously carried out concomitantly with the filtration.

BASF's "60th Anniversary of Povidone" published in **July of 1999**, teaches the melt extrusion (i.e., **"compounding"**) of **PVPP** with other compounds. **Beverage treatment applications are clearly mentioned under a section labeled "Miscellaneous Applications," as indicated in the annotated copy of page 4 above**:


duction 11, 2897 (1996). Besides pharmaceutical uses, technical grades of PVP are used throughout the industry. Applications cover cosmetics and toiletries, beverage filtration, photographic products, dyeing applications and inks, detergents, dispersions, suspensions and emulsions, adhesives, paints and coatings, and paper manufacturing.

In view of **BASF's "60th Anniversary of Povidone,"** it would have been obvious to one skilled in the art to melt extrude (i.e., compound/mix) known filtration aids, such as the polyolefins, polypropylene or polyethylene taught by **Van Den Eynde**, for example, with **PVPP,** to practice the invention of **Butterworth** and/or **Van Den Eynde**, in order to obtain the benefits **Butterworth** extols:

ABSTRACT

The present invention provides an improved process for increasing the chill haze stability of aqueous liquids derived from fruits and vegetables, (e.g., beer, wine, fruit juices, vinegar, etc.) by **using one or more haze control agents in a precoat or after precoat layer in the filter media used to filter the liquid and by adding one or more haze control agents as a body feed upstream of the filter**. In a preferred embodiment one or more haze control agents are also added in ruh storage at a time in the process significantly before the filtration step. **This improved process permits the beverage to be packaged immediately after filtration, thus eliminating the time consuming and space consuming storage following filtration normally required by conventional chill haze control techniques.**

in addition, that **Van Den Eynde** teaches is preferred. Both **Van Den Eynde** and Butterworth clearly teach that is desirable/preferred to perform the filtration and stabilization in a single step.

The huge ranges of percentages claimed cover almost the entirety of possibilities. Absent a showing of criticality or unexpected result specifically associated the extremely broad ranges claimed, the selection of any combination of percentages would have been readily apparent to the skilled artisan, given the teachings of these references.

Claim Rejections - 35 USC § 112

Claims **11,13-16** and **18-27** are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for ***"simultaneous"*** treatment, does not reasonably provide enablement for treatment that is **not simultaneous**. Moreover, claims 11 and 16, by virtue of evidence claims 12 and 17, are intended to "cover" or "read-on" **both** ***"simultaneous"*** and ***"non-simultaneous"*** treatment. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. Dependent claims **12** and **17** specify ***"simultaneous"*** stabilization of the liquid being treated. Given the nature of the resultant ***"compounded"*** materials, as argued by Applicants throughout the prosecution of this application, it is unclear how anything but simultaneous treatment can be accomplished. The specification sheds no light on this matter.

Given the disclosure, and the arguments made during prosecution, for example:

> 10/509,641 Drohmann 53383
>
> *Handbook of the Society of the Plastics Industry*, chapter 22, page 635, 1991, New York, also explains "[t]he process by which ingredients are intimately melt-mixed together into as nearly a homogeneous mass as is possible is known as compounding." On pages 645 – 646, the reference, further explains,
>
> - "[s]trictly speaking, compounding involves the fusion of different materials into a homogeneous mass, uniform in composition and structure;"
> - in compounding, "the more mobile materials are locked up inside a tough, viscous, doughy envelope;" and
> - "[t]he use of heat, either internally generated by shear or externally applied is needed to obtain compound uniformity."
>
> Still further, the Declaration under 37 C.F.R. §1.132, executed July 12, 2006, evidences that compounding is fundamentally different from admixing. In the declaration,

one skilled in the art would not know from the specification/disclosure, how to practice anything other than **"simultaneous"** treatment.

Claims **11-27** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what specific manipulative steps Applicants regard as their invention.

It is unclear how dependent claims **12** and **17** further limit the claims from which they depend.

In claims **14** and **25**, it is unclear what Applicants intend by the recitations ***"polyvinylpolypyrrolidone"*** and **"PVPP"** It is unclear how these recitations differ and/or compare to the recitations ***"polyvinylpyrrolidone"*** and/or **"PVP."** It is unclear how the structures of these compounds differ. Applicants' arguments submitted on **May 19, 2009,** pertaining to the **"PVPP"** of **Butterworth** have raised these issues.

Response to Arguments

Applicants' arguments with respect to claims **11-27** have been considered but are moot in view of the new ground(s) of rejection.

Applicants have argued:

> Furthermore, the Office action asserts Butterworth discloses the use of PVPP admixed with conventional filter aids to treat liquids. The claims, however, employ crosslinked polyvinyllactams. **Butterworth does not teach the use of crosslinked PVPP.** This claim feature seems to have been overlooked.

From **Sax's Dangerous Properties of Industrial Materials (11th Edition) Volumes 1-3**:

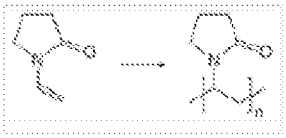
PKQ150 **HR: D**
POLYVINYLPOLYPYRROLIDONE
PROP: White, hygroscopic powder; faint bland odor. Insol in water.
SYNS: CROSPOVIDONE □ PVPP □ 1-VINYL-2-PYRROLIDONE CROSSLINKED INSOLUBLE POLYMER
SAFETY PROFILE: When heated to decomposition it emits acrid smoke and irritating fumes.

Also, see **Wikipedia**:

Polyvinylpyrrolidone

From Wikipedia, the free encyclopedia

Polyvinylpyrrolidone (**PNVP**, **PVP**, **povidone**, **polyvidone**) is a water-soluble polymer made from the monomer *N*-vinylpyrrolidone:



Polyvinylpolypyrrolidone (**PVPP**, **crospovidone**) is a highly cross-linked modification of PVP.

PVPP is a crosslinked polyvinyllactam. That claim feature was not overlooked.

Applicants next argue:

> **Finally, with respect to claim 11 (and the claims that depend from claim 11), the Office action fails to address the requirement that a suspension must be passed through a porous filter medium at a constant flow rate.**

Here Applicants raise the issue of ***"constant flow rate,"*** which was thought to have been put to bed back in 2006. For Applicants' convenience, their **Remarks of September 18, 2006**, pertaining to ***"constant flow rate"*** are repeated here:

> Applicants respectfully assert that it is common practice in the beverage industry and well known to the one skilled in the art that filtration is performed by at least the following steps:
>
> a) a filter aid is added to the turbid beverage, usually by continuous dosage;
>
> b) the turbid beverage with the filter aid is the allowed to pass an auxiliary filter. The filter aid and the haze causing particles ("haze") of the beverage, e.g. yeast cells, settle on the auxiliary filter and form a filter cake.
>
> c) past the filter yields a clear beverage.
>
> In step b), settling of filter aid and haze on already formed filter cake is a continuous process. Thus, during the filtration, the filter cake is continuously growing in thickness. The thicker the filter cake the higher a resistance to the flow is generated.
>
> Further, Applicants respectfully assert that changes in the flow rate, especially when appearing suddenly, are unwanted as this could lead to a breakage of the filter cake and consequently immediate filtration stoppage. Therefore, the pressure in front of the filter is increased continuously so far that the resistance of the filter cake is compensated for as it grows and the flow rate is kept constant.
>
> This procedure is summarized in, for example, pages 334 to 337 of *Filtration - principles*
>
> Page 5 of 10

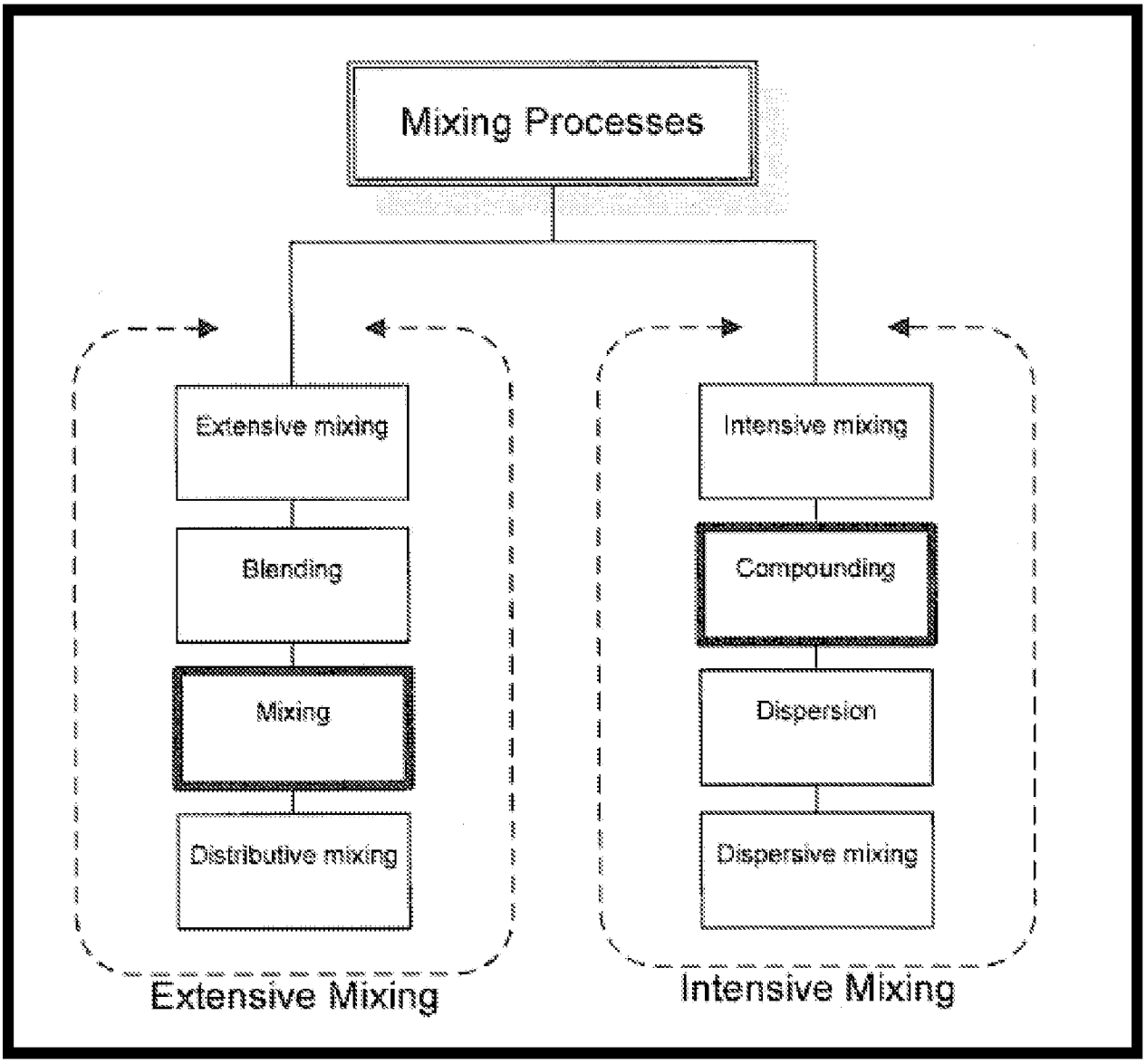
and practices (Chemical industries; v. 27), M. J. Matteson, C. Orr (eds.), 2nd edition, Marcel Dekker, New York, 1987 (attached hereto). Moreover, methods performing the aforementioned filtration method employing a constant rate are everyday practice in the beverage industry and thus, the one skilled in the art knows how to adjust the pressure to keep the flow rate constant.

Surely the claimed **"constant flow rate"** does not justify the grant of a United States Patent.

Applicants argue:

The Office action alleges the specification equates the terms "mixing" and "compounding." Applicants respectfully submit this allegation is in error. The portions of the specification cited on pages 5 and 7 of the Office action do not equate the terms. The specification uses the terms in harmony with the substantive evidence of record, which indicates compounding is divergent and fundamentally different, even on the most basic level, from admixing.

Then, provide an illustration that clearly shows **"compounding"** to be a **"mixing process"**:



Surely, Applicants must see the inconsistency in this line of argument.

For the record, the examiner has alleged nothing. The examiner formulated the rejection in light of the terms as defined in Applicants specification. As defined in Applicants' specification:

> Compounding is generally mixing a polymer with at least one additive (Der Doppelschneckenextruder : Grundlagen- und Anwendungsgebiete [The double-screw extruder : Principles and areas of application], edited by: VDI-Gesellschaft Kunststofftechnik.-Düsseldorf : VDI-Verlag, 1995, Chapter 7 and

> The filter aids are comminuted after the mixing process by techniques of pelletizing, shredding and/or grinding, preferably by a sequence of pelletizing and grinding. At the temperature profile of a cold grinding process, water may remain in the final product.

As is clear from these excerpts, Applicants (and not the examiner) have equated the terms ***"mixing"*** and ***"compounding,"*** and have used the terms interchangeably. If Applicants intended something more to be read into the term ***"compounding,"*** the specification should have made that clear. As Applicants are undoubtedly aware, an applicant may be his own lexicographer. And he must live with that definition. Applicants have devoted a considerable portion of their remarks to this issue of "compounding." Several extrinsic sources have been referenced in an effort to redefine the term to have it interpreted in a certain way. Nevertheless, there is no need to look to extrinsic sources, as it is clear from Applicants' disclosure what was intended by the term ***"compounding."***

> **For that reason, claims "must be read in view of the specification, of which they are a part." Id. at 979. As we stated in Vitronics, the specification "is always highly relevant to the claim construction analysis. *Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.*" 90 F.3d at 1582.**

For these reasons, the ***after-the-fact*** attempt to re-define the term ***"compounding,"*** cannot be found to be persuasive.

All of these arguments are moot. Anniversary clearly teaches melt extrusion, primarily in the context of a pharmaceutical application, while at the same time on the same page before and after the discussion of melt extrusion, discussing beverage treatment applications. One skilled in the beverage treatment would have easily made the logical leap, and readily appreciated that the same melt extrusion process could be used to make beverage treatment compositions. Why else would beverage treatment applications twice be mentioned on that page?

It is submitted that the balance of the arguments are moot in view of the new grounds of rejection.

Any inquiry concerning this communication should be directed to /Robert James Popovics/ at telephone number (571) 272-1164.

/Robert James Popovics/
Primary Examiner
Art Unit 1797